REMARKS

In the Official Action dated April 6, 2004, claims 22-23, 25-28 and 30 have been rejected under 35 U.S.C § 103 as allegedly unpatentable over Elliott *et al.*, WO 00/50380 and Busch *et al.*, WO 97/42190 or Urban, U.S. Patent No. 5,359,068. In an Advisory Action dated June 25, 2004, the Examiner maintained these rejections.

In the June 25, 2004 Advisory Action, the Examiner did not enter Applicant's proposed amendments alleging that these amendments do not place the claims in better form for appeal. The Examiner further provides reasoning stating that Busch *et al.* discloses that the dosage for the atypical antipsychotic, ziprasidone, can be in the range of 5-300 mg/day. Applicant respectfully disagrees.

Claim 22 has been amended to incorporate the elements of claim 26. Claim 26 has been cancelled, without prejudice. Specifically, the phrase "wherein the atypical antipsychotic agent, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg per day to about 1500 mg per day, and the antidepressant, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg per day to about 1500 mg per day" was added to claim 22. Busch *et al.* do not mention the combination of an atypical antipsychotic and an antidepressant, with or without the ranges disclosed in the amended claims.

This Response addresses each of the Examiner's rejections and objections. Accordingly, the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 22-23, 25-28 and 30 have been rejected under 35 U.S.C § 103, as allegedly unpatentable over Elliott *et. al.*, WO 00/50380 and Busch *et. al.*, WO 97/42190 or Urban, U.S. Patent No. 5,359,068. The Applicants respectfully traverse.

The pending claims relate to a method of treating depression, obsessive disorder, and psychosis in a mammal, comprising administering to said mammal: (a) a compound that exhibits activity as an SRI antidepressant, or a pharmaceutically acceptable salt thereof; and (b) an atypical antipsychotic or pharmaceutically acceptable salt; wherein the active agents "a" and "b" above are present in amounts that render the combinations of the two agents effective in treating, respectfully, depression, obsessive compulsive disorder, and psychosis, wherein the atypical antipsychotic agent, or pharmaceutically acceptable salt thereof, is administered in amounts from about 0.05mg per day to about 1500mg per day, and the antidepressant, or pharmaceutically acceptable salt thereof, is administered in amount from about 0.05mg per day to about 1500mg per day.

The subject matter of the present invention is patentably distinct from the separate and collective teachings of the prior art. The prior art references do not teach, disclose or even suggest the present invention. Moreover, there is no suggestion in the prior art to combine the references in a manner that the Examiner has recommended nor does this combination of references result in the claimed invention.

Claims 22-23, 25-28 and 30 have been rejected under 35 U.S.C §103, as allegedly unpatentable over Elliot, *et al.*, WO 00/50380 and Busch, *et al.*, WO 97/42190 or Urban, U.S. Patent No. 5,359,068. The Applicant respectfully traverses.

For purposes of expediting prosecution, Claim 22 has been amended to incorporate the elements of claim 26. Claim 26 has been cancelled, without prejudice. Specifically, the phrase "wherein the atypical antipsychotic agent, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg per day to about 1500 mg per day, and the antidepressant, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg day to about 1500 mg per day" was added to claim 22. No new matter has been added.

Elliot, *et al.* disclose methods of treating depression, anxiety disorders, and obsessive-compulsive disorders, in a mammal comprising administering to said mammal in need of such treatment SRI inhibitors such as [2-(3,4-Dichlorophenoxy)-5-fluorobenzyl]-methylamine. Although Elliot, *et al.* disclose using SRI inhibitors to treat depression, anxiety disorders, and obsessive-compulsive disorders, Elliot, *et al.* do not disclose or suggest combining an atypical antipsychotic with an SRI antidepressant "wherein the atypical antipsychotic agent, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg per day to about 1500 mg per day, and the antidepressant, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg day to about 1500 mg per day." Furthermore, Elliot, *et al.* do not motivate one skilled in the art to arrive at combining an atypical antipsychotic with an SRI antidepressant "wherein the atypical antipsychotic agent, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg per day to about 1500 mg per day, and the antidepressant, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg day to about 1500 mg per day," as claimed Elliot *et al.* fail to disclose both (1) the combination of an atypical antipsychotic

with an SRI antidepressant and (2) the amount of atypical antipsychotic and SRI antidepressant administered, which is an amount from about 0.05 mg day to about 1500 mg per day for each. And to the extent that Elliot et al. only discloses SRI inhibitors, Elliot *et al.* teach away from the present invention. Accordingly, the claimed invention is patentable over Elliot, *et al.*

Busch *et al.* and Urban each disclose using ziprasidone to treat anxiety. However, neither Busch, *et al.* nor Urban disclose or suggest combining an atypical antipsychotic with an SRI antidepressant "wherein the atypical antipsychotic agent, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg per day to about 1500 mg per day, and the antidepressant, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg day to about 1500 mg per day." Furthermore, neither Busch, *et al.* nor Urban motivate one skilled in the art to combine an SRI antidepressant and an atypical antipsychotic "wherein the atypical antipsychotic agent, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg per day to about 1500 mg per day, and the antidepressant, or pharmaceutically acceptable salt thereof, is administered in an amount from about 0.05 mg day to about 1500 mg per day," as presently claimed. Busch, *et al.* and Urban fail to disclose both (1) the combination of an atypical antipsychotic with an SRI antidepressant and (2) the amount of atypical antipsychotic and SRI antidepressant administered, which is an amount from about 0.05 mg day to about 1500 mg per day for each. And to the extent that Busch, *et al.* and Urban only discloses using ziprasidone to treat anxiety, Busch, *et al.* and Urban teach away from the present invention. Accordingly, the claimed invention is patentable over Elliot, *et al.* The Examiner has

offered no reference on the record which suggests combining an SRI antidepressant with an atypical antipsychotic.

It is well settled that in determining obviousness, the inquiry is not whether each element of the invention existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed. Hartness International, Inc. v. Simplistic Engineering Company, 819 F.2d 1100, 2 U.S.P.Q. 2d 1826 (Fed. Cir. 1987). One skilled in the art would not seek the teachings of Elliot, *et al.*, Busch, *et al.*, or Urban, in an effort to achieve the present invention, whether in combination with the primary reference, or otherwise; and the Examiner has provided no convincing reason why such a combination would be obvious to one skilled in the art. None of the cited references provide any incentive or encouragement to combine the references as recommended by the Examiner; nor does this specific combination result in the claimed invention. Accordingly, it is improper for the Examiner to combine the cited references, where the references do not suggest such combination, in order to reject Applicants' invention under 35 U.S.C. § 103. ACS Hospital Systems, Inc. v. Montefiore Hosp., 732 F.2d 238, 147 U.S.P.Q. 391 (CCPA 1965), reversed a hindsight rejection and stated:

> The ever present question in cases within the ambit of 35 U.S.C. § 103 is whether the subject matter as a whole would have been obvious to one of ordinary skill in the art following the teachings of the prior art at the time the invention was made. It is impermissible within the framework of 35 U.S.C. § 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.

Wasslau, 353 F.2d at 241, 147 U.S.P.Q. at 393. (Emphasis added).

Again, as stated by the CCPA in In re Imperato, 486 F.2d 585, 587, 179 U.S.P.Q. 730, 732 (1973) "...the mere fact that those disclosures can be combined does not make the combination obvious unless the art also contains something to suggest the desirability of the combination." (Emphasis in original; citation omitted). Applicant respectfully submits that the Examiner impermissibly chose bits and pieces from various prior art references and combined those bits and pieces in a manner not remotely suggested by the references themselves. There is absolutely no indication to combine Elliot et al. with the secondary and tertiary references.

Thus, in view of the foregoing amendments and remarks, the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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